

REMARKS

Claims 1-21, 29-45 and 54-59 were previously pending for examination with claims 1, 29, 37 and 54 being independent claims; claims 8-13 have been withdrawn. By this amendment, claim 37 has been amended; claims 1-21, 29-36, 38 and 54-59 have been cancelled; and claims 60-64 have been added. Accordingly, claims 37, 39-45 and 60-64 are now pending. No new matter has been added.

Applicant acknowledges the courtesies extended by Examiner Matthews during telephone interviews with the undersigned attorney on January 15, 2008 and February 25, 2008. The substance of the interviews is summarized in the remarks set forth below.

Rejections Under 35 U.S.C. §102

Claims 1-3, 14-16, 18, 20, 54 and 58 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Orgill (WO 00/16822). Applicant respectfully traverses these rejections.

In the office action, the examiner asserts that Orgill discloses a tissue repair prosthesis comprising polypropylene repair fabric completely surrounded by a barrier layer and peripheral barrier as claimed, citing an example at page 16 of the reference. (Office Action, page 3). Applicant respectfully disagrees.

Orgill is directed to a structural biomaterial including a polypropylene mesh integrated with a biodegradable matrix. (Abstract). In one example, Orgill discloses the preparation of a collagen-glycosaminoglycan/polypropylene graft by surrounding a polypropylene mesh with a highly porous matrix of collagen-glycosaminoglycan. (Page 16, lines 5-23). However, as indicated during the interview of January 15, one of ordinary skill in the art would readily appreciate that Orgill does not teach or suggest a prosthesis that includes an adhesion resistant barrier layer and either an adhesion resistant peripheral barrier (claim 1) or a layer of repair fabric with an adhesion resistant outer peripheral edge (claim 54). Rather, as indicated above and discussed throughout Orgill, the CG matrix is *highly porous* to allow cellular infiltration that results in tissue ingrowth to the matrix. (See, e.g., page 9, lines 8-28; page 10, lines 10-16; page 14, lines 13-15).

As indicated during the interview, the Orgill CG matrix has structural properties that are in complete contradiction with the structural characteristics of an adhesion resistant material or structure as understood by one of ordinary skill in the art, which have been explained in prior

responses and the Eldridge Declaration. In this regard, it is clear from the teachings of Orgill that the matrix is specifically intended to allow cell infiltration and tissue ingrowth and is not adhesion resistant. Thus, one of ordinary skill in the art would readily appreciate that the Orgill prosthesis does not employ either a barrier layer or a peripheral barrier/outer peripheral edge that inhibits the formations of adhesions, as required by independent claims 1 and 54.

During the interview, the examiner referred to page 7, line 30 through page 8, line 3 of Orgill as somehow supporting the rejection on the basis that Orgill does disclose an adhesion resistant barrier that inhibits adhesions. Applicant respectfully submits these few lines do not indicate that the CG matrix inhibits adhesions to itself, particularly when considered within the context of the entire disclosure.

Notwithstanding the foregoing and without acceding to the propriety of the rejections, Applicant has canceled claims 1-3, 14-16, 18, 20, 54 and 58 solely to advance prosecution of this application. Accordingly, the rejection of these claims as being anticipated by Orgill is moot and should be withdrawn.

Rejections Under 35 U.S.C. §103

Claims 1-7, 14-17, 20, 29-35, 37-44, and 54-58

Claims 1-7, 14-17, 20, 29-35, 37-44, and 54-58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meier (U.S. Patent No. 3,416,524) in view of Ory et al. (U.S. Patent No. 6,264,702).

As indicated during the discussion on February 25, Applicant has canceled claims 1-7, 14-17, 20, 29-35 and 54-58 solely to advance prosecution of this application. Claim 37 remains the sole independent claim for examination. Applicant respectfully traverses the rejection of claim 37 and its dependent claims.

Independent claim 37 is directed to an *implantable prosthesis* including, *inter alia*, a layer of repair fabric and a barrier layer configured to inhibit the formation of adhesions between at least a portion of a surface of the repair fabric and adjacent tissue and organs. The layer of repair fabric has an outer margin with an outer peripheral edge. The outer margin of the layer of repair fabric has been melted and resolidified to render the entire thickness of the outer peripheral edge resistant to the formation of adhesions with tissue and organs.

Reply to Office Action dated August 31, 2007

Meier is directed to a non-adherent surgical dressing including a laminated pad 13 with a cellulosic layer 14 and a resin fiber layer 15. The cellulosic layer has moisture absorption properties while the resin fiber layer has a porous surface which serves as the non-adherent contact surface for the wound and which permits free flow to moisture. The pad is surrounded by an edge frame or crown 12 which stabilizes the edges of the cellulosic layer and the resin fiber layer.

In the office action, the examiner acknowledges that Meier fails to disclose that the frame 12 inhibits the formation of adhesions with tissue or organs thereto. (Office Action, page 4). In an effort to address this deficiency, the examiner looks to Ory which discloses an implantable prosthesis including a layer of repair fabric 4 and an absorbable barrier layer 3. Ory indicates that the barrier layer projects beyond the fabric layer in such a way as to protect the prosthesis from visceral contacts. (Col. 4, lines 26-30).

In the office action, the examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the frame of Meier to comprise a material that is adhesion resistant, in view of Ory, to inhibit the formation of adhesions with adjacent organs after implantation. Applicant respectfully disagrees.

One of ordinary skill in the art would not have been led to modify Meier in view of Ory.

The alleged motivation or reason for modifying the Meier frame finds no support in the record. In particular, as discussed above and indicated during the interview of January 15, Meier is directed to a **surgical dressing** which is used, as one of ordinary skill in the art would readily appreciate, to cover a surface wound. Meier is **not** an implantable prosthesis that would be implanted adjacent internal tissue or organs. Consequently, there simply would have been **no reason** for one of skill in the art to even contemplate, let alone to have been led, to modify the Meier frame so as to inhibit the formation of adhesions with adjacent organs after implantation as contended in the office action.

In the office action, the examiner states that each of the Meier and Ory devices is directed toward tissue wound defects. (Office Action, page 2). Without acceding to this characterization of Meier and Ory, this still does not change the fact that Meier is a surgical dressing for covering surface wounds. In the office action, the examiner also refers to Orgill for the proposition that one of ordinary skill in tissue repair would readily look to external and internal tissue repair

Reply to Office Action dated August 31, 2007

structures. Applicant respectfully submits that even if Orgill supports this proposition, it is not clear at all as to how this supports the rejection. There is simply no teaching or suggestion to employ Meier as an implantable prosthesis or that Meier is even capable of being employed as an implantable prosthesis. Therefore, even assuming one of ordinary skill would somehow consider external and internal tissue repair structures when contemplating devices for tissue wound defects, the examiner's alleged motivation or reason to modify the Meier frame (i.e., to inhibit the formation of adhesions with adjacent organs *after implantation*) finds no support whatsoever in the record as Meier is not an implantable prosthesis and there is no suggestion to implant the Meier dressing. Consequently, there is no apparent reason supported by Meier and Ory, or provided by any other evidence, to employ an adhesion resistant frame with the Meier dressing.

Additionally, as indicated during the January interview, Ory does not teach or suggest an implantable prosthesis that is configured to inhibit adhesions to the peripheral edge of the repair fabric. In this regard, although the barrier layer of the Ory prosthesis projects beyond the repair fabric, there is no teaching or suggestion that the layer is maintained across any portion of the fabric edge so as to protect the peripheral edge from forming adhesions with adjacent tissue and organs as asserted in the office action. Ory also does not express any desire to prevent the formation of adhesions to the outer peripheral edge of the fabric. Rather, one of ordinary skill in the art would appreciate from Fig. 1 that the outer peripheral edge of the Ory fabric 2 is exposed and would be subjected to tissue ingrowth and adhesion formation from at least the mesh side of the prosthesis.

In the office action, the examiner states that Meier already teaches maintaining the peripheral barrier across the entire thickness of the outer peripheral edge, referring to Figure 4 of Meier, and further states that Ory need not teach this feature. The examiner also states that Ory is provided in the rejection to teach the modification of the Meier frame to be adhesion resistant to protect the edge, which would be achieved by non-porous features of the material employed with Ory. (Office Action, page 2). Applicant respectfully disagrees.

There must be an apparent reason that finds support in the record that would have led one of ordinary skill in the art to provide an adhesion resistant frame with the Meier dressing. As indicated above and during the interview, Meier employs the frame to stabilize the edges of the cellulosic layer and the resin fiber layer. In this regard, Meier discloses that the frame provides freedom from fraying, loose fibers and delamination which were purported to be undesirable

Reply to Office Action dated August 31, 2007

problems of prior surgical dressings. (Col. 1, lines 21-30 and col. 2, lines 51-56). Nowhere does Meier teach or suggest that the frame is provided to protect the peripheral edge of the cellulosic layer, which the examiner contends is the fabric layer, from adhesions, despite the fact that the dressing is provided with a non-adherent contact surface for a wound.

In contrast, Ory discloses an implantable prosthesis that includes a layer of repair fabric with an exposed outer peripheral edge. Thus, as indicated during the interview, the one reference relied upon by the examiner that is an implantable prosthesis (i.e., Ory) does not even disclose an adhesion resistant peripheral barrier that is maintained across the entire thickness of the outer peripheral edge of the repair fabric. Consequently, the examiner has failed to establish any apparent reason based on the reference teachings or other evidence that would have led one of ordinary skill in the art to employ an adhesion resistant frame on the Meier dressing.

In the office action, the examiner states that Meier discloses that the crown or frame comprise an inert thermoplastic resin, and asserts that "inert" implies that the structure would not promote adhesions. (Office Action, page 2). Although Meier discloses that the frame may be made of an inert thermoplastic material such as polypropylene (Col. 2, line 69 to col. 3, line 3), this does not in any way imply that the frame would not promote adhesions, as asserted by the examiner. In this regard, it is well known to repair a tissue or muscle wall defect, such as a hernia, with an implantable repair mesh fabricated from polypropylene monofilament, an inert material, where the mesh allows tissue ingrowth and forms adhesions to repair a tissue defect. The fact that a material may be inert is not determinative as to whether or not it is adhesion resistant. As indicated in prior responses and the Eldridge Declaration, the adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors including the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis.

Furthermore, as indicated above, any modification of the Meier frame to employ an adhesion resistant material in view of Ory, as contended in the office action, would involve the use of an absorbable material for the frame. However, there is no teaching or suggestion that employing an absorbable material would be desirable for the Meier frame. Rather, one of ordinary skill in the art would have appreciated that the use of an absorbable material for the Meier frame would result in an absorbable frame that may potentially lead to fraying, loose fibers and delamination, in contrast to the teaching of Meier for even using the frame.

In the office action, the examiner states that modifying the Meier frame to be adhesion resistant would be achieved by the non-porous features of the material employed with Ory, rather than the absorbable features of the Ory material. (Office Action, page 2). Thus, the examiner appears to take the position that Ory's teaching of using an absorbable material for the barrier layer is irrelevant to an obviousness analysis. Applicant respectfully disagrees.

It is well established that the prior art must be considered in its entirety and that it is improper to pick and choose only certain aspects of the prior art teachings. In this regard, while Ory discloses the use of an adhesion resistant barrier layer, Ory employs an absorbable material for the barrier layer. Ory does not teach or suggest the use of a non-absorbable material for the barrier. In fact, as indicated during the interview, Ory believes that a barrier made of a non-absorbable material can itself be the source of adhesions. (Col. 1, lines 50-52). Thus, to the extent that one of ordinary skill in the art would somehow have even been led to employ an adhesion resistant peripheral barrier in view of Ory, one of ordinary skill in the art would have been led to employ only an absorbable material for such a barrier based on the express teachings of Ory.

In view of the foregoing, Applicant respectfully submits that a *prima facie* case of obviousness has not been established in the office action. Meier and Ory do not provide any apparent reason that would have led one of ordinary skill in the art to modify the Meier frame in the manner suggested in the office action. Applicant respectfully submits that any assertion that it would have been obvious to modify Meier in view of Ory would appear to be the result of improper hindsight reconstruction in view of Applicant's claimed invention. Accordingly, the rejection of independent claim 37 under §103 in view of Meier and Ory is improper and should be withdrawn.

Claims 39-44 depend from claim 37 and are patentable for at least the same reasons.

The claims patentably distinguish over Meier in view of Ory.

For the sake of argument only, even were one of ordinary skill in the art to have somehow been led to modify the Meier frame to be formed of an adhesion resistant material in view of Ory, the claims patentably distinguish over the references.

As indicated above, claim 37 is directed to an implantable prosthesis. In contrast, Meier is directed to a surgical dressing, not an implantable prosthesis as contended in the office action. As indicated in Applicant's prior response, Meier provides no teaching or suggestion that the surgical dressing can be or is even capable of being used as an implantable prosthesis. Thus, independent claim 37 patentably distinguishes over the modification of Meier in view of Ory such that the rejection of claim 37 under §103 should be withdrawn for at least this additional reason.

In the office action, it is unclear why the examiner has maintained the current rejection in view of this distinction between claim 37 and Meier as the examiner did not respond to Applicant's prior argument concerning this distinction. In any event, the examiner has established no basis that the Meier dressing is or could be employed as an implantable prosthesis.

In the office action, the examiner contends that Meier discloses a peripheral barrier that may be melted and resolidified. Without acceding to this characterization of Meier, as indicated during the telephone discussion of February 25, Applicant respectfully submits that Meier does not teach or suggest melting and resolidifying the outer margin of the layer of repair fabric, which the examiner contends is the cellulosic layer 14, to render the entire thickness of the outer peripheral edge of the repair fabric resistant to the formation of adhesions with tissue and organs as recited in claim 37. Rather, Meier indicates that the separately formed outer frame, not a layer of repair fabric, may be softened so that it tends to merge with adjacent loose fibers or frayed edges of the pad. (Col. 3, lines 10-16). As indicated during the discussion of February 25, softening the outer frame is *not* melting and resolidifying the outer margin of the layer of repair fabric, as required by the claim. Thus, claim 37 patentably distinguishes over Meier and Ory such that the rejection under §103 should be withdrawn for at least this additional reason.

During the February discussion, the examiner suggested that claim 37 may not clearly express this distinction. Applicant respectfully disagrees. Nevertheless, claim 37 has been amended to further clarify this aspect of the claimed subject matter.

As amended, claim 37 recites that the layer of repair fabric includes a plurality of tissue infiltratable interstices that are constructed and arranged to allow tissue ingrowth thereto, which was previously recited in claim 38. The claim has also been amended to recite that the outer margin of the layer of repair fabric has been melted and resolidified to substantially eliminate the tissue infiltratable interstices therein and render the entire thickness of the outer peripheral edge

of the layer of repair fabric substantially impervious to tissue ingrowth so that the outer peripheral edge is resistant to the formation of adhesions with tissue and organs. Claim 37 has also been amended to clarify that the barrier layer inhibits tissue ingrowth and the formation of adhesions with tissue and organs thereto.

In view of the foregoing, claim 37 patentably distinguishes over Meier and Ory, taken either alone or together, which fail to teach or suggest an implantable prosthesis that includes a layer of repair fabric with the claimed features. Thus, the rejection of claim 37 under §103 should be withdrawn for at least this additional reason.

Claims 39-44 depend from claim 37 and are patentable for at least the same additional reasons.

Claims 18, 19, 21, 36, 45 and 59

Claims 18, 19, 21, 36, 45 and 59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meier in view of Ory and further in view of Sharber (U.S. Patent No. 6,075,180).

Claims 18-21, claim 36 and claim 59 have been canceled solely to advance prosecution of this application such that the rejection of these claims is moot and should be withdrawn.

Without acceding to the propriety of the reference combination suggested by the Examiner, claim 45 depends from claim 37 and is patentable for at least the same reasons set forth above. Accordingly, the rejection of claim 45 under §103 should be withdrawn.

Additional Claims

Claims 60-64 have been added to further define aspects of Applicant's invention. These claims depend from claim 37 and are patentable for at least the same reasons set forth above.

Reply to Office Action dated August 31, 2007

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By: James M. Hanifin, Jr.
James M. Hanifin, Jr., Reg. No. 39,213
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

Docket No.: D0188.70125US00

Date: 2/28/08